ALBUMIN

In Vitro diagnostic reagent, for professional use only

CLINICAL SIGNIFICANCE (1-8)
Albumin, synthesised primarily by the liver, represents 50 to 60% of total serum proteins. Because of its small size and its high plasmatic concentration, albumin is the major protein component of most extravascular body fluid, including CSF, interstitial fluid, urine and amniotic fluid. Albumin’s primary function is the maintenance of colloidal osmotic pressure in both extra vascular and vascular spaces, with continuous equilibration. Albumin also binds and transports a large number of compounds (ions, free fatty acids, bilirubin, drugs...). Albumin is a mobile reserve of amino acids.

Increased levels of albumin are present only in acute dehydration, especially critical for newborn. Hypoalbuminemia is seen in a multitude of diseases bound to different pathological states: 1) acute and chronic inflammation, 2) decreased synthesis: hepatic insufficiency, malnutrition, analbuminemia, 3) increased loss: nephritic syndrome, gastrointestinal loss, sever and large burns, bedsore, 4) increased catabolism: fever, hyperthyroidism...

METHOD (6-8)
Colorimetric
Bromocresol green (BCG)

PRINCIPLE (6-8)
Colorimetric determination of serum albumin using bromocresol green at pH 4.20.

\[
pH = 4.20
\]

Albumin + BCG \rightarrow \text{Albumin-BCG complex}

REAGENTS COMPOSITION
Reagent : R
Sucinate buffer, pH 4.20 87 mmol/L
Bromocresol green 0.2 mmol/L
Brij 35 7.35 mL/L

Standard : Std
Bovine albumin 5 g/dL 50 g/L

MATERIAL REQUIRED BUT NOT PROVIDE
CONT-0060 ELITROL I 10 x 5 mL
CONT-0160 ELITROL II 10 x 5 mL

PRECAUTIONS
- The standard contains less than 0.1 % sodium azide. Sodium azide can react with copper and lead plumbing to form explosive metal azides. If discharge in the canalisations, rinse with plenty of water.
- Use clean or single use par laboratory equipment only to avoid contaminations.
- The standard should be immediately and tightly capped to prevent contamination and evaporation.

WASTE MANAGEMENT
Disposal of all waste material should be in accordance with local and legal requirements.

STABILITY OF REAGENTS
To store at 2-25 °C and protected from light.
The reagent and the standard are stable until the expiry date stated on the label.

On board stability:
The stability is specific for each analyser (for Selctra refer to § PERFORMANCE DATA).

PREPARATION AND STABILITY OF WORKING REAGENT
The reagent and the standard are ready to use

SAMPLES (4,5)
- Specimen
  Serum.
  Heparinized plasma.
- Storage
  Analyze fresh serum or store them at 4 ºC less than 72 hours.
  Stored at -20 ºC, sera are stable for 6 months.
  For a longer storage, freeze samples at -70 ºC.

REFERENCE VALUES (3)
Ambulatory patients
Patients at rest
3.8 - 5.5 g/dL 3.5 - 5.2 g/dL
38 - 55 g/L 35 - 52 g/L

Note: It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only an indication.

PROCEDURE
This reagent can be used on most analysers, semi-automated analysers and manual method.
The applications are available on request.

Wavelength: 600 nm
Temperature: 37 ºC
Read against reagent blank.

BLANK CALIBRATION TEST
Reagent R1 310 µL 310 µL 310 µL
Distilled water 2 µL - -
Standard 2 µL - -
Sample - 2 µL -
Mix and read the absorbance (A) after a 25 second incubation.

CALCULATION
\[
A_{\text{Sample}} \times n = A_{\text{Standard}} \times n
\]

CALIBRATION
Albumin standard is traceable to the Certified Reference material, CRM 470.
The calibration frequency is specific for each analyser (for Selectra refer to § PERFORMANCE DATA).

QUALITY CONTROL
To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) are recommended.

PERFORMANCE DATA at 37 ºC on Selectra
- Analytical range
  The reagent is linear from 1.5 to 6 g/dL (15 to 60 g/L).
- Detection limit (9)
  Determined according to SFBC protocol, the detection limit is equal to 0.1 g/dL (1 g/L).

References:
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<td>ALBU- 0600 2 x 125 mL</td>
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- **Analytical Sensitivity**
The average variation of the analytical signal is $134 \times 10^{-3} \Delta A$ per g/dL of albumin (or $13.4 \times 10^{-3} \Delta A$ per g/L), for a light path of 1 cm.

- **Precision**

  **Within-run reproducibility**
  - **Low level:** $n = 20$, $m = 2.58$ g/dL, $CV = 1.7\%$
  - **Medium level:** $n = 20$, $m = 3.54$ g/dL, $CV = 1.2\%$
  - **High level:** $n = 20$, $m = 4.54$ g/dL, $CV = 1.2\%$

  **Between-run reproducibility**
  - **Low level:** $n = 20$, $m = 2.65$ g/dL, $CV = 2.6\%$
  - **Medium level:** $n = 20$, $m = 3.41$ g/dL, $CV = 2.1\%$
  - **High level:** $n = 20$, $m = 4.39$ g/dL, $CV = 1.9\%$

- **Correlation**
A comparative study has been performed between ELITech method and another commercial reagent (Bromocresol green (BCG) method) on 31 human serum samples. The sample concentrations were between 1.07 and 6.11 g/dL.

The parameters of linear regression are as follows:

  - **Correlation coefficient:** $(r) = 0.9984$
  - **Linear regression:** $y = 0.911x + 0.35$ g/dL

- **Interferences**
According to SFBC recommendations some studies have been performed to determine the level of interference from different compounds:

  - **Unconjugated Bilirubin:** No significant interference up to 36 mg/dL (360 mg/L, 616 µmol/L).
  - **Conjugated Bilirubin:** No significant interference up to 25 mg/dL (250 mg/L, 427 µmol/L).
  - **Ascorbic acid:** No significant interference up to 40 mg/dL (400 mg/L, 2.2 mmol/L).
  - **Haemoglobin:** No significant interference up to 500 mg/dL (5 g/L) on normal sera.
  - **Glucose:** No significant interference up to 500 mg/dL (5g/L, 27 mmol/L).
  - **Turbidity:** No significant interference up to 600 mg/dL Triglycerides equivalent (6g/L, 6.9 mmol/L).
  - **Sodium salicylate:** No significant interference up to 250 mg/dL (2.5 g/L).

Other compounds may interfere. (10-12)

- **On board stability/Calibration frequency on Selectra (no refrigerated)**

  - **On–board Stability:** 14 days (Capped vials and stored at 2-25 °C during the night)
  - **Calibration frequency:** 14 days

Make A new calibration when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

**BIBLIOGRAPHY**


**SYMBOLS USED ON LABELS**

- **IVD**: In vitro diagnostic medical device
- **CIf**: Consult Instruction for use
- **MA**: Manufacturer's address
- **REF**: Catalogue number
- **TI**: Temperature limitation
- **LOT**: LOT number
- **EXP**: Expiration date

Revised Version: PIT-ALBU-11 01/2010